DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

JAN 20 2006

Fred H. Rodriquez Jr., M.D.
President
American Society for Clinical Pathologists
1225 New York Avenue, NW
Suite 250
Washington, DC 20005

Dear Dr. Rodriquez:

Thank you for participating in the conference call on December 29, 2005, which we requested in order to discuss issues related to cytology proficiency testing and requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The discussions we had, as well as those with other cytology professionals, have been very productive in helping to chart a course by which we can clear up misapprehensions and find better ways to improve the quality of pathology services.

In our discussions, you requested a continuation of the educational approach to enforcing the cytology proficiency testing requirements in 2006 that we previously followed in 2005. We also received a written request to that effect from the College of American Pathologists (CAP), and are sending a similar reply to Dr. Sodeman of CAP.

We believe your recommendation has merit. Continuation of proficiency testing, together with continuation of the educational approach, will maintain appropriate emphasis on both education and quality, while enabling laboratories to build on their testing experiences in order to optimize individual proficiency of Pap smear examinations. We view such proficiency testing as an important protection of women's health and expect continued improvement based on the testing results we have seen so far. We therefore hope you can appreciate why we cannot endorse the College's earlier request for suspension of testing, as a suspension would impair the improvements in proficiency that are occurring now as a result of the testing, and would not provide the ensurance of proficiency envisioned by this key requirement of CLIA.

Under the educational approach, laboratories will not be cited for deficiencies or have sanctions imposed against their CLIA certificate for failure to comply with the cytology PT requirements, provided they:

- Enroll all affected individuals (i.e., cytotechnologists and pathologists) in a Centers for Medicare & Medicaid Services' (CMS) approved testing program for the calendar year testing cycle; and

- Ensure that all such individuals are tested within 2006, in accordance with the regulatory protocol and timeframes specified under Federal regulations at 42 CFR 493.855. This section identifies the extent to which additional testing, education, or limitations must be put in place with regard to individuals who do not pass the test initially.

We will issue the appropriate instructions to State survey agencies shortly. Continuation of the educational approach to the enforcement of the cytology PT requirements will permit laboratories and individuals to continue to enhance their skills through training and education. This approval also provides CMS the opportunity to compile and evaluate the testing and performance data from 2005 and 2006, and work with the laboratory community to identify how the cytology PT regulatory requirements might be improved.

Together with the Centers for Disease Control and Prevention, we are also engaging a workgroup under the auspices of the Secretary's Clinical Laboratory Improvement Advisory Committee to advise us on testing standards, including scoring methods, in order to address issues of concern expressed by the cytology community, and to ensure that proficiency testing requirements are as effective and as appropriate as possible. We will continue to seek input from various parties, including the CLIA workgroup, on how we might accelerate the process of identifying how the cytology PT requirements might be improved.

I appreciate that the CAP has concerns about the diagnostic criteria used in the cytology PT program. These criteria are based on the Bethesda System (an industry-wide standard for reporting the results of cervical cytology) which was confirmed by the National Institute of Health Consensus Conference in 2001, and reported in the Journal of the American Medical Association in 2002. Nonetheless, if it is possible to craft a better testing system, and if we can work together to build consensus on the various issues raised, I will work within the CLIA statutory parameters to expedite the conversion of such ideas into reality.

Finally, I wish to thank all affected laboratories for their efforts to ensure and demonstrate proficiency in gynecological cytology examinations. I realize that fulfillment of the legal requirements for proficiency testing was not an easy undertaking in 2005. However, over 96 percent of affected laboratories enrolled, were able to accomplish the proficiency testing for the 2005 cycle, and are continuing to show improvement in performance on the part of individuals tested. Such responsiveness to the CLIA statutory requirement exemplifies the professionalism of the Nation's cytotechnologists and pathologists.

I know we share a deep commitment to promote and protect the health and safety of women. It is also evident that we have some different points of view. Yet I am confident we can find a way to build on the progress that has been made recently and make further improvements. We welcome the opportunity to work with laboratory professionals and key professional organizations such as yours.

Sincerely,

Mark B. McClellan, M.D., Ph.D.

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Administrator
Washington, DC 20201

JAN 20 2006

Thomas M. Sodeman, M.D., FCAP
President
College of American Pathologists
1350 I Street, NW., Suite 590
Washington, DC 20005-3305

Dear Dr. Sodeman:

Thank you for your letter requesting a continuation of the educational approach to enforcing the cytology proficiency testing (PT) requirements in 2006 that we previously followed in 2005.

We believe your recommendation has merit. Continuation of proficiency testing, together with continuation of the educational approach, will maintain appropriate emphasis on both education and quality, while enabling laboratories to build on their testing experiences in order to optimize individual proficiency of Pap smear examinations. We view such proficiency testing as an important protection of women's health and expect continued improvement based on the testing results we have seen so far. We therefore hope you can appreciate why we cannot endorse the College's earlier request for suspension of testing, as a suspension would impair the improvements in proficiency that are occurring now as a result of the testing, and would not provide the ensurance of proficiency envisioned by this key requirement of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Under the educational approach, laboratories will not be cited for deficiencies or have sanctions imposed against their CLIA certificate for failure to comply with the cytology PT requirements, provided they:

- Enroll all affected individuals (i.e., cytotechnologists and pathologists) in a Centers for Medicare & Medicaid Services' (CMS) approved testing program for the calendar year testing cycle; and

- Ensure that all such individuals are tested within 2006, in accordance with the regulatory protocol and timeframes specified under Federal regulations at 42 CFR 493.855. This section identifies the extent to which additional testing, education, or limitations must be put in place with regard to individuals who do not pass the test initially.

We will issue the appropriate instructions to State survey agencies shortly. Continuation of the educational approach to the enforcement of the cytology PT requirements will permit laboratories and individuals to continue to enhance their skills through training and education. This approval also provides CMS the opportunity to compile and evaluate the testing and performance data from 2005 and 2006, and work with the laboratory community to identify how the cytology PT regulatory requirements might be improved.

Together with the Centers for Disease Control and Prevention, we are also engaging a workgroup under the auspices of the Secretary's Clinical Laboratory Improvement Advisory Committee to advise us on testing standards, including scoring methods, in order to address issues of concern expressed by the cytology community, and to ensure that proficiency testing requirements are as effective and as appropriate as possible.

We appreciate the improved communication resulting from recent conversations with the CMS Survey and Certification Group, with other members of my staff and essential members of the College of American Pathologists (CAP) and the American Society for Clinical Pathology. These discussions as well as those with other cytology professionals have been very productive in helping to chart a course by which we can clear up misapprehensions and find better ways to improve the quality of pathology services. We will continue to seek input from various parties, including the CLIA workgroup, on how we might accelerate the process of identifying how the cytology PT requirements might be improved.

We also appreciate that the CAP has concerns about the diagnostic criteria used in the cytology PT program. These criteria are based on the Bethesda System (an industry-wide standard for reporting the results of cervical cytology) which was confirmed by the National Institute of Health Consensus Conference in 2001, and reported in the Journal of the American Medical Association in 2002. Nonetheless, if it is possible to craft a better testing system, and if we can work together to build consensus on the various issues raised, I will work within the CLIA statutory parameters to expedite the conversion of such ideas into reality.

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Sincerely,

Mark B. McClellan, M.D., Ph.D.